

Remarks

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Claims 20-39 are currently pending in the application, including independent claims 20 and 30 and withdrawn claims 30-40. For instance, independent claim 20 is directed to an implantable fixed tissue comprising cross-linked elastin. More specifically, the elastin of the implantable fixed tissue is cross-linked with a phenolic tannin cross-linking agent. Accordingly, the implantable fixed tissue includes a residue of the phenolic tannin cross-linking agent from the cross-linking reaction.

In the Office Action, claims 22 and 25-27 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, claim 27 was rejected as failing to include sufficient antecedent basis. Applicant submits that amended claim 27 provides proper antecedent basis for all limitations of the claim.

Claims 22 and 25-27 were rejected as being indefinite for being defined in terms of properties alone. Functional language does not, in and of itself, render a claim improper. Moreover, utilization of functional language in a claim has been found acceptable when it sets definite boundaries on the patent protection sought. (MPEP §2173.05(g)). Applicants respectfully submit that the functional language of dependent claims 22 and 25-27 is acceptable, as this language sets definite boundaries on the patent protection being sought. In addition, these claims depend from independent claim 20, which includes structural limitations of the claimed implantable fixed tissue and as such, the implantable fixed tissue of the claims has not been defined in terms of functional properties alone. Accordingly, Applicants submit that the claims fully comply with 35 U.S.C. §112, second paragraph and request withdrawal of this rejection.

In the Office Action, claims 20, 21, and 23-24 were rejected under 35 U.S.C. §102(b) as anticipated by, or, in the alternative under 35 U.S.C. §103(a) as obvious over Bachhuber, et al. (U.S. Patent No. 4,588,579). In addition, claims 22 and 25-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bachhuber, et al.

Applicants respectfully submit that the pending claims patentably define over the cited reference for at least the reason that Bachhuber, et al. fails to disclose or suggest

certain limitations of the claims. For example, Bachhuber, et al. fails to disclose or suggest an implantable fixed tissue including a residue of a phenolic tannin cross-linking agent, as is found in the pending claims.

Bachhuber, et al. is directed to methods for the production of thin section of biological tissue, and especially for production of such for transmission electron microscopy. The process includes fixing the tissue, dehydrating the tissue by infiltration of a hardenable medium miscible with water, and embedding of the infiltrated tissue into a casting resin prior to the cutting of the thin sections (col. 1, ll. 5-54). As described in Example 1, the tissues are also treated for contrasting purposes. Specific materials utilized in the disclosed processes include distilled water and uranyl acetate, among others. The utilization of the materials of Bachhuber, et al. according to the treatment processes can successfully render the tissues suitable for examination via, e.g., electron microscopy. However, as many of these reagents are toxic (e.g., uranyl acetate), the disclosed processes will also render the tissues non-implantable.

As discussed in the pending application at paragraph 42, tannic acid has been utilized in the past as an elastin stain for electron microscopy and has been used as a contrast-increasing agent for collagen staining. Bachhuber, et al. is directed to and describes just such an application, i.e., preparation of a tissue sample for electron microscopy or other similar types of examination. This is evidenced at column 1, lines 34-41 of the patent where the fixation methods suitable for the disclosed tissues are described as those disclosed in the book, "Principles and Techniques of Electron Microscopy" (M.A. Hayat, Van Nostrand Resinhold, New York, 1970) (col. 1, ll. 34-41), which describes preparation of tissue samples to be investigated, rather than preparation of tissue samples to be implanted. Hence, the tissues of Bachhuber, et al. have been prepared for examination, not implantation, and during that preparation process, the tissues of Bachhuber, et al. have also been rendered unimplantable. Bachhuber, et al. does not disclose or suggest utilizing the disclosed processes for preparation of implantable tissues, as are found in the pending claims.

When taken as a whole, Bachhuber, et al. does not disclose or suggest implantable fixed tissues including the residue of a phenolic tannin cross-linking agent,

as are found in the pending claims. Accordingly, Applicants maintain that the pending claims patentably define over Bachhuber, et al.

In the Office Action, claims 20-21, 23-24, and 28 were rejected under 35 U.S.C. §102(e) as anticipated by, or, in the alternative under 35 U.S.C. §103(a) as obvious over Adkisson (U.S. Patent No. 6,645,764). In addition, claims 22 and 25-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adkisson.

Applicants respectfully submit that the pending claims patentably define over the cited reference for at least the reason that Adkisson fails to disclose or suggest certain limitations of the claims. For example, Adkisson fails to disclose or suggest an implantable fixed tissue including a residue of a phenolic tannin cross-linking agent, as is found in the pending claims.

Figure 6 of Adkisson shows the characterization by transmission electron microscopy of a neocartilage matrix developed according to the methods of the patent. Representative cultures of the matrix were fixed with glutaraldehyde, post-fixed with osmium-tetroxide, and stained en-bloc with tannic acid and uranyl acetate (col. 5, l. 66 – col. 6, l. 9). The patent thus describes utilization of tannic acid as a stain for preparation of materials for electron microscopy as discussed in the pending application at paragraph 42. As both osmium-tetroxide and uranyl acetate are toxic materials, however, the tissue cultures of Adkisson that have been stained with tannic acid have also been rendered non-implantable. Applicants find no additional reference to utilization of tannic acid in the patent. Accordingly, Applicants maintain that Adkisson does not disclose or suggest implantable fixed tissues including the residue of a phenolic tannin cross-linking agent, as are found in the pending claims. Accordingly, Applicants maintain that the pending claims patentably define over Adkisson.

As a final matter, Applicants respectfully request rejoinder of withdrawn claims 30-40 to the pending application. The claims are related as subcombination/combination claims. Such claims require two-way distinctness for maintenance of a restriction requirement. Specifically, the inventions are distinct if it can be shown that a combination as claimed (A) does not require the particulars of the

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subcombination as claimed for patentability and (B) the subcombination can be shown to have utility either by itself or in another materially different combination (MPEP §806.05(c)). In the present instance, Applicants submit that the combination as claimed in independent claim 30 requires the implantable fixed tissue as claimed in the subcombination of independent claim 20. Accordingly, the two-way distinctness requirement has not been met, and Applicants request rejoinder of the claims.

It is believed that the present application is in complete condition for allowance and favorable action is therefore requested. Examiner Kumar is invited and encouraged to telephone the undersigned at her convenience should there be any questions with regard to this application.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,
DORITY & MANNING, P.A.

6/30/06

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